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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,457	03/09/2001	Nonda Katopodis	NK3	7046

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/802,457	Katopodis
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-18* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Claims 1-18 are pending and examined on the merits.

Claim Objections

2. Claims 17 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 17 and 18 are drawn to the method of claim 1. However, the embodiments of claim 17 and 18 include additional species of bodily fluid not recited in claim 1.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rendered indefinite by the recitation of the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). For purpose of examination, the claim will be read as ---body fluids selected from the group consisting of cerebrospinal fluid, urine, saliva and sputum and determining the amount of lipid associated sialoprotein...---

Claims 17 and 18 are rejected for lacking an active method step relating the comparison of the lipid-associated sialoproteins levels with the diagnosis of cancer. For purpose of examination, the claims will be read as relating the elevation of lipid-associated sialoprotein levels with the diagnosis of cancer.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for de-lipidating sialoproteins recovered from cerebrospinal fluid, urine, saliva and sputum, does not reasonably provide enablement for a method of selectively extracting lipid-associated sialoproteins from non-lipid associated sialoproteins isolated from cerebrospinal fluid, urine, saliva and sputum. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. Upon analysis of the specification and the active method steps of claim 1 it is concluded that other sialoprotein species such as free sialoprotein or protein-bound sialoprotein would be present in the upper phase along with lipid associated sialoprotein that would be effectively separated from said lipid component in the lower organic phase with the alkyl hydrocarbons. The specification does not provide for the removal of the non-lipidated hydrocarbons prior to the lipidated hydrocarbons or vice versa. As the result of carrying out the active method steps of claim 1, both formerly lipidated and non-lipidated sialoproteins will be present in the aqueous layer, therefore, the specification is enabling for a method of extracting sialoproteins from cerebrospinal fluid, urine, saliva and sputum, not for a method of extracting only lipid-associated sialoproteins from cerebrospinal fluid, urine, saliva and sputum. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to practice the claimed invention.

7. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 18 is drawn to a method of diagnosing cancer in a human subject comprising determining at

regular time intervals the amount of lipid associated sialoprotein in a sample of the subject's cerebrospinal fluid, peritoneal fluid, pleural fluid, bronchial washings, saliva or sputum. However, the specification provides no guidance on when to being said determinations, or the time intervals between each determination. The art teaches histological diagnosis of brain cancer after the onset of symptoms, therefore, it cannot be relied upon for teachings regarding the appropriate time prior to the development of tumors to begin the sampling of cerebrospinal fluids, the time intervals between sampling, or for the criteria for identifying patients at risk for developing brain or spinal cord tumors (Burger et al, Neurol Clin, 1991, Vol. 9, pp. 249-271; Ross et al, Surg Neurol, 1991, Vol. 36, pp. 431-440). Given this lack of teaching in the specification or any art of record, one of skill in the art would be subject to undue experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katopodis (US 5,045,453) in view of Gernez-Rieux et al (Pathologie et Biologie, 1963, Vol. 11, pp. 729-741). Claims 1-16 are drawn in part to a method for extracting sialoprotein from sputum. Katopodis et al teach the exact method of claims 1-16 for extracting sialoprotein from serum and plasma. Katopodis et al do not teach a method of extracting sialoprotein from sputum. Gernez-Rieux et al teach the determination of sialoprotein in the sputum of patients having chronic bronchitis and asthma as a measurement of disease state (page 730, Tableau III). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Katopodis for the determination of sialoprotein in sputum of patients

having bronchitis and asthma. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Gernez-Rieux et al on the correlation between sialoproteins and bronchitis and asthma.

10. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katopodis (US 5,045,453) in view of Bellahcene et al (British Journal of Haematology, 2000, Vol. 111, pp. 1118-1121). Claims 1-17 are drawn in part to a method of diagnosing cancer in a human subject comprising determining the amount of sialoprotein in peritoneal fluid. Katopodis et al teach the exact method of claims 1-16 for extracting sialoprotein from serum and plasma. Katopodis et al do not teach a method of extracting sialoprotein from peritoneal fluid. Bellahcene et al teach a method for the detection of multiple myeloma comprising the detection of sialoprotein in an ascites sample (page 1119, last line to page 1120, first column, line 3). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Katopodis for the detection of sialoprotein in peritoneal fluid. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Bellahcene et l on the diagnosis of multiple myeloma by the detection of sialoprotein in ascites fluid.

11. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katopodis (US 5,045,453) in view of Figarella-Branger et al (Cancer Research, 1990, Vol. 50, pp. 6364-6370) or Rao et al (Trans All-India Institute of Mental Health, 1969, Vol. 9, pp. 35-38). Claims 1-17 are drawn in part to a method of diagnosing cancer in a human subject comprising determining the amount of sialoprotein in cerebrospinal fluid.

Katopodis et al teach the exact method of claims 1-16 for extracting sialoprotein from serum and plasma. Katopodis et al do not teach a method of extracting sialoprotein from cerebrospinal fluid.

Figarella-Branger et al teach the detection of medulloblastoma metastatses by measuring highly sialylated isoforms of N-CAM protein in the cerebrospinal fluid of patients (page 6369, second column, last paragraph).

Rao et al teach the detection of spinal tumors comprising the measurement of sialic acid (N-acetyl neuraminic acid) in cerebrospinal fluid. Rao et al do not specifically teach that the sialic acid residues being detected are in the form of sialoprotein, however, it is reasonable to assume that the detection of sialic acid in cerebrospinal fluid does not exclude the detection of sialoproteins.

It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Katopodis for the determination of sialoprotein in cerebrospinal fluid. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Figarella-Branger et al or Rao on the correlation of sialoproteins in the cerebrospinal fluid and the diagnosis of cancer.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Patent Examiner, Group 1642
February 11, 2002

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